Order Now! "The Wuhan Cover-Up" by RFK Jr.!

12/20/23 • COVID • BIG PHARMA › NEWS

Court Pauses CHD Lawsuit, Gives FDA Until April 2025 to Hand Over Analysis of COVID Vaccine Injuries

The Freedom of Information Act lawsuit brought by Children's Health Defense seeks records relating to the U.S. Food and Drug Administration's analysis of adverse events related to COVID-19 vaccines, based on the agency's active monitoring of large healthcare databases.

By Brenda Baletti, Ph.D.

16

Miss a day, miss a lot.** Subscribe to The Defender's Top News of the Day. **It's free.

Donate Now
You make the difference.

Latest News

600 Military Installations Are Leaking Toxic PFAS Chemicals Into U.S. Drinking Water Supplies

Author of Study Used to Vilify Unvaxed Had Ties to Pfizer — New Peer-Reviewed Research Shows Why the Study Was Flawed

Obesity Rising + Sleep Quality & Behavior + 'Natural' Autism Therapy + More

MORE NEWS

Latest Views

Is Gluten Making You Sick? Or Is It the Glyphosate Sprayed on Wheat?

Keeling Over on the Soccer Field: Is It 'Long COVID' — or the Vaccines?

House Set to Grill Fauci Next Month — Will He Come Clean About COVID Origins?

MORE VIEWS

Get FREE News & Updates!

First Name..
Last Name..
Email..
SIGN UP

Get Text Alerts
Sign up for breaking news from The Defender.
Currently only eligible for numbers in the U.S. and Canada.
1234567890
Phone
REQUIRED. Phone number must be in a standard 10-digit format: 1234567890 or 123-456-7890
CONTINUE

A federal court last week granted the U.S. Food and Drug Administration's (FDA) request to pause legal proceedings until April 2025 in a Freedom of Information Act (FOIA) lawsuit brought by Children's Health Defense (CHD) against the agency.

CHD sued the FDA after the agency failed to respond to a FOIA request submitted in September 2022, seeking records relating to the agency's active monitoring of large healthcare databases, including insurance claims databases, for analysis of some adverse events reported after the COVID-19 shots.

This is at least the third FOIA lawsuit seeking the FDA's analysis of adverse events possibly linked to the COVID-19 shots where the FDA has asked the judge to pause proceedings until 2025, and the second, so far, where the judge has agreed.

The agency claims that given the hefty demands of the court-ordered release of FOIA documents related to the licensing of the Pfizer and Moderna shots — documents that it was legally required to make immediately available for public disclosure upon granting the licenses — it simply doesn't have the "bandwidth" to address any other "complex" FOIA requests related to the COVID-19 vaccines until at least mid-2025.

Federal agencies typically have 20-30 business days to respond to FOIA requests.

"It is disappointing that a court again has agreed the FDA can circumvent its obligations to timely respond to FOIA requests, preventing CHD and U.S. citizens access to documents of critical importance to understanding the agency's actions and inactions during the COVID-19 pandemic," Kim Mack Rosenberg, acting general counsel for CHD, told The Defender.

"Allowing the FDA to dodge accountability lays the groundwork for similar secrecy in the future as FDA continues to hide the ball," she added.

The other two lawsuits, filed by the Informed Consent Action Network (ICAN) and CHD, requested documentation related to the FDA and Centers for Disease Control and Prevention's (CDC) analysis of reports made to the Vaccine Adverse Event Reporting System (VAERS).

A court granted the stay in ICAN's case. A decision on the requested stay in CHD's case is still pending.

The lawsuit in which the judge granted a stay last week seeks FDA analysis of a different dataset.

The FDA in early 2021 began an active-safety monitoring program to investigate possible causal links between the COVID-19 shots and certain symptoms or events called adverse events of special interest (AESI). AESIs are of "special interest" because they identify side effects the agency believes might be caused by the shots.

In addition to VAERS — a passive system where people report data that the agencies analyze — the FDA also proactively seeks out and analyzes millions of records contained in large healthcare data systems.

It analyzes that data to see if there are safety signals for AESIs, which allows it to verify safety issues identified elsewhere and detect additional signals it may not find in VAERS.

In FDA protocols established in February 2021, the agency underscored the importance of active monitoring:

> "Active monitoring is essential because it allows us to assess potential associations between vaccine exposure and adverse events in near-real time, determine if more comprehensive analyses should be conducted, and provide timely information to support regulatory decision-making processes."

CHD argued in its opposition memo that the FDA's continuing failure to produce the requested records puts the public, which needs to know about problems with the shots to make informed decisions, at risk, writing:

> "Information about FDA's active investigation of possible causal links between COVID-19 injections and adverse events remains important for members of the public, who are still faced with decisions about whether to take COVID-19 shots and boosters, whether to vaccinate their children, and whether to politically support vaccine mandates."

However, the court sided with the FDA, agreeing that it is entitled to an "Open America" stay, which can be granted to allow an agency time to process a FOIA in its existing backlog when the agency shows it is exercising "due diligence" to meet those demands and it faces "exceptional circumstances" that could not have been anticipated and in which to do so.

CHD argued the FDA is not demonstrating due diligence and that the "exceptional circumstances" the FDA faces, where it is required to attend to an increased number of FOIA requests regarding the COVID-19 vaccine, were entirely predictable.

Brian Hooker, Ph.D., CHD's senior director of science and research, told the Defender it is essential for scientists to have access to FDA and CDC data in order to do their own analysis of the real effects of the vaccines.

Hooker said:

> "The gold standard of post-marketing surveillance of vaccine safety is CDC's Vaccine Safety Datalink, which is safely tucked away at the CDC — like Fort Knox — from any independent scientists. This is despite the fact that it is supported by $30 million per year of taxpayer dollars.
>
> "The only recourse for these scientists would be FOIAing the AESI data from FDA, which is much more comprehensive than the woefully under-reported, much maligned CDC VAERS database.
>
> "If the federal government was interested in transparency in any way, shape, or form, they would execute this FOIA request in a timely fashion and open up the Vaccine Safety Datalink to independent scientists.
>
> "What is it that they're actually hiding?"

"The Wuhan Cover-Up"
by Robert F. Kennedy Jr.
ORDER NOW

'A problem of the FDA's own making'

In early 2021, the FDA began an active safety-monitoring program to investigate possible causal links between COVID-19 shots and certain AESIs.

In September 2022, CHD submitted a FOIA requesting the FDA's records related to that investigation, but the FDA never provided the records.

Shortly after CHD submitted its request, the FDA said it may not be able to respond within the 20-30 day time limit allowed under FOIA and it also denied CHD's expedited processing request.

FDA failed to respond to several follow-up inquiries, although it did indicate CHD's request was clear and didn't need any further clarification. It also informed CHD the request had been assigned to its "'complex' queue" and wouldn't be assigned for processing for at least 24 months.

In August, CHD filed a lawsuit seeking to compel FDA to process the request.

Today, CHD's request is stuck in the FDA's "complex processing queue," which the complaint says is one of six queues maintained by the Access Litigation and Freedom of Information Branch (ALFOI).

ALFOI is the FOIA-processing subdivision of the Center for Biologics Evaluation and Research (CBER), the center in the FDA that regulates vaccines.

The FDA alleges that ALFOI is struggling to meet its current FOIA obligations because it has received a substantially higher number of requests since 2019 and in particular, the burden of meeting the Public Health and Medical Professionals for Transparency (PHMPT) FOIA lawsuits — mandating the FDA release the Pfizer documents and the Pfizer and Moderna documents regarding licensure of Comirnity and Spikevax shots — were placing a heavy burden on the agency, which was compelled to release at least 35,000-55,000 pages per month.

CHD argued, in opposition, that "the challenge ALFOI faces in managing its current workload is a problem of the FDA's own making," and it does not exempt the FDA from its responsibility to produce documents requested under FOIA "promptly."

The agency is responsible for delegating the work in such a way as to meet those requests, CHD wrote.

RFK Jr. and Brian Hooker's *New* Book: "Vax-Unvax"
ORDER NOW

CHD's request is 'locked in cold storage' at FDA

The FDA claimed it is exercising "due diligence" to respond to CHD's request, but is struggling under the weight of increased caseloads and lawsuits.

However, attorneys for CHD said a closer look at agency-wide FOIA metrics since 2014 paints a different picture.

First, the average number of FOIAs has not increased steadily but rather has gone up and down.

The FDA increased the number of staff dedicated to processing FOIAs from approximately 120 full-time people in 2014 to 163 in 2022. Spending on FOIA requests by the FDA has dropped sevenfold since 2014 and the average time of response has increased.

Since 2021, the backlog for requests and the number of administrative appeals to compel compliance have increased.

When the FDA receives a FOIA request, the agency assigns it to the subdivision that maintains the records sought — in this case, the request went to ALFOI at CBER, where all vaccine-related requests go.

Only the number and complexity of requests to CBER's ALFOI division have increased continually since early 2020, but the FDA did not begin adding more staff there until 2022.

When ALFOI receives requests, it places them in one of six different processing queues based on the volume, complexity or subject matter. CHD's request was placed in the "complex" line, which contains requests that the FDA deems will require extensive time to process.

By the end of fiscal year 2022, according to the FDA, ALFOI had a backlog of 532 requests in total and 370 of them were in the "complex processing queue."

"That is" CHD wrote, "the complex processing queue contained at least 70% of the total backlog for all six ALFOI queues, and 9% of the FDA's entire FOIA backlog."

The FDA claimed it is exercising "due diligence," but the demands are simply too high.

CHD countered that the U.S. attorney general's own FOIA guidelines state that "Timely disclosure of records is … essential to the core purpose of FOIA." It added that the Open America lawsuit the FDA cites as grounds for delaying the lawsuit itself stated "excessive delay by the agency in its response is often tantamount to denial."

CHD alleged the problem lies in how the FDA organizes its work to process the requests, not in the number of requests. Decisions made at the FDA demonstrate a lack of due diligence that leaves FOIA requests within ALFOI's complex processing queue unattended.

It wrote:

> "The [FDA's] declaration does not address the question of how many individuals within ALFOI's limited workforce the FDA has dedicated to processing the backlog, but the answer appears to be straightforward: not enough.
>
> "Indeed, given the 24-plus-month wait before requests in the complex queue are even assigned for processing, 'processing queue' is a misnomer; 'locked in cold storage' more aptly describes the status of ALFOI's complex requests.
>
> "The fact that ALFOI assigns incoming requests to one of six processing queues does not show due diligence, where one of the queues is virtually at a standstill."

'FDA's excuses ring hollow'

To justify an Open America stay, the FDA must show it faces "exceptional circumstances" — which means it has experienced a "deluge" of requests that exceeds what would have been anticipated and that its existing resources are inadequate to deal with such a volume.

Congress was specific in making this definition narrow — it does not apply to a predictable agency workload of requests. The agency must show the number of requests is "truly unforeseen and remarkable," according to CHD's memo.

But, CHD alleged, given that the number of average requests has decreased annually, the workforce has grown and the costs have gone down, the FDA can't reasonably argue overall that it faces exceptional circumstances.

Further, the current workload was not "unforeseen."

"For over three and a half years, the FDA has been aware of the public's keen interest in the agency's pandemic-related activities and of CBER's activities in particular, and aware of the need to obtain and allocate sufficient resources," CHD wrote.

The production levels associated with the PHMPT litigation — the primary basis for the FDA's claim — is also not a surprise, it said, because the FDA's own regulations say that when the FDA approves a vaccine, licensing information must be immediately available for public disclosure.

The FDA has known from the outset that when it licensed the COVID-19 vaccines, it would have to disclose records regarding safety and effectiveness data, study protocols, and adverse reaction reports publicly and also that requests for licensing records would go to CBER, where ALFOI would face that work, CHD wrote.

The need for greater staff became even more obvious, CHD alleged, when PHMPT submitted a FOIA requesting those records on Aug. 27, 2021, and ultimately on Jan. 6, 2022, when the court denied the FDA's request for 75 years to produce the records.

Similar requests and lawsuits, CHD argued, should not have come as a surprise to the FDA, nor should the need for more staff within ALFOI.

CHD added that the FDA's $8.4 billion budget — a $54 million increase over 2022 — FDA didn't lack resources to meet the request or time to redirect resources toward meeting ALFOI FOIA demands.

"Open America does not give the agency license to shift the cost of its mistakes to CHD," the complaint said.

Rosenberg said CHD's request was a straightforward one and the court's decision was concerning.

"CHD did not ask the court to micromanage the FDA but simply asked the court to appropriately apply well-established legal standards concerning federal agencies' obligations under FOIA," she said. "FDA's excuses ring hollow and the court having accepted them and not requiring transparency from FDA is deeply concerning," she added.

Your support helps fund this work, and CHD's related advocacy, education and scientific research.
DONATE NOW

FDA also seeking 'Open America' stay in CHD's FOIA lawsuit for VAERS analysis

CHD is still waiting for the judge's decision in another pending FOIA lawsuit against FDA. In that case, the FDA is again asking a federal judge to let it wait at least 18 more months before providing key analyses, conducted in 2021 and 2022, of the VAERS database.

In that case, CHD filed a FOIA request in July 2022, asking the FDA for records of the data-mining analysis the agency conducted to identify safety signals in VAERS that might indicate links between the COVID-19 shots and adverse events.

CHD also requested records of any FDA review of serious AESIs, along with records of the FDA's communications with VAERS staff and the CDC regarding that agency's own COVID-19 vaccine safety monitoring, and records of follow-up investigations of safety signals.

In October 2022, the FDA told CHD it would not provide any of the information, claiming the information was exempt because it contained "opinions, recommendations and policy discussions" protected by law.

CHD appealed that decision in November 2022 and then followed up with a lawsuit. FDA is also seeking an Open America stay in that case.

The FDA has received (and denied) at least two other FOIA requests for the Empirical Bayesian (EB) data mining records — one from ICAN, and one from The Epoch Times — according to CHD's memo in that case, which have also gone unfulfilled.

And the agency in September refused to provide Sen. Ron Johnson (R-Wis.) with the data-mining analysis after he requested it in January, The Epoch Times reported.

"FDA's EB data mining analyses of adverse events contained in VAERS reports for COVID-19 vaccines are currently the subject of pending FOIA [Freedom of Information Act] litigation," the agency told the Senator.

"FDA is unable to comment on pending litigation or provide information or data that is currently being considered in pending litigation," it added.

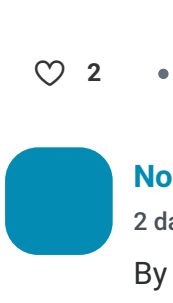
Johnson told FDA Commissioner Robert Califf in a letter that the FDA could not withhold that information from him.

"As you are well aware, Congress has a right to information contained at U.S. federal agencies as it conducts its constitutional oversight responsibilities," Johnson told The Epoch Times.

"It is outrageous that FDA would assert that pending litigation, and particularly FOIA litigation, would allow your agency to obstruct my congressional oversight," he added.

Subscribe to The Defender – It's Free!
First Name.. Last Name.. Email.. SIGN UP

SUGGEST A CORRECTION



Brenda Baletti, Ph.D.
Brenda Baletti Ph.D. is a reporter for The Defender. She wrote and taught about capitalism and politics for 10 years in the writing program at Duke University. She holds a Ph.D. in human geography from the University of North Carolina at Chapel Hill and a master's from the University of Texas at Austin.

Sign up for free news and updates from Children's Health Defense. CHD focuses on legal strategies to defend the health of our children and obtain justice for those injured. We can't do it without your support

Republishing Guidelines

Children's Health Defense Comment Policy
We welcome relevant and respectful comments. Off-topic comments may be removed.
Please read our Comment Policy before commenting.
Got it

16 Comments

1 Login ▾

Join the discussion…

LOG IN WITH OR SIGN UP WITH DISQUS ?

Name

♡ 2 • Share Best Newest Oldest

Nod
2 days ago
By 2025, the pandemic treaty will be in place, and this information will be irrelevant. That is the point of this.

Courts are corrupt. All branches of government are corrupted by globalism.

7 0 Reply • Share ›

GarySummers → Nod
2 days ago
"CIA/NIH Fauci, Peter Daszak, Ralph Baric, fully need to be Investigated!"

"Japanese Scientists Find Indisputable Evidence That ALL COVID Variants Are Man-Made"
https://thehighwire.com/edi...

"David Martin presents hard evidence showing COVID-19 is a man-made bioweapon."
https://podcasts.apple.com/...

"American scientists misled Pentagon on research at the Wuhan Institute of Virology"
https://usrtk.org/covid-19-...

0 0 Reply • Share ›

BChristine
3 days ago
Bastards; 2025?? It is obvious who the FDA is in bed with ... evidence can easily be skewed by that time!

6 0 Reply • Share ›

GarySummers → BChristine
2 days ago edited
"BREAKING" 'Sharing Is Caring' *Held Accountable ??*
""Peter Daszak" and "Baric, Ralph S.""
"American Scientists "Misled" Pentagon on research at the Wuhan Institute of Virology"

"American researchers concealed their intention to conduct high-risk coronavirus research in Wuhan under lax safety standards from the Pentagon the year before the COVID-19 pandemic, according to documents obtained by U.S. Right to Know. "

A 2018 grant proposal called "Project DEFUSE", coauthored by the Wuhan Institute of Virology and "American Scientists", has stoked concern that the "pandemic resulted from a lab accident."

It proposed engineering high-risk coronaviruses of the same species as SARS and SARS-CoV-2. Most worrying to some scientists: The proposal involved synthesizing spike proteins with "furin cleavage sites" — "the same feature that supercharged SARS-CoV-2 into the most infectious pandemic pathogen in a century. Indeed, some scientists have likened DEFUSE to a blueprint for generating SARS-CoV-2 in the lab."
https://usrtk.org/covid-19-...

0 0 Reply • Share ›

Ektor
3 days ago
What a freaking joke. FDA and courts are paid off for sure.

6 0 Reply • Share ›

Ralyn Speerly Schraceo
3 days ago
Apparently they're trying to hide it. This all needs stopped and people held accountable - they knew, because I knew simply by reading all the pdfs on FDAs website before it was released, that they were dangerous. They also knew that they were blocking real treatments that worked while forcing remdeciphere (or however it's spelled) on everybody.

5 0 Reply • Share ›

seahawk
3 days ago
Does anyone get it yet. The court systems today are not about any kind of justice. The courts serve what ever political side they are on. They are profoundly corrupt. FDA is stalling for time because the real data will show they are either incompetent or criminal or both. Human governments' necks are all on the chopping block and their executioner will arrive soon.

4 0 Reply • Share ›

Polly Green
3 days ago
FDA = Favorite Deceivers Agency

4 0 Reply • Share ›

Daniel Arnaud → Polly Green
3 days ago
FDA = Fraud and Death Administration
CDC = Covid Disinformation Center

8 0 Reply • Share ›

bernard b carman → Polly Green
2 days ago
AMA = American Murder Association

1 0 Reply • Share ›

trmlogan
2 days ago
What?? 2025????? The idea that 1 judge can hand out favors that flaunt regulations put in place to protect the people is absolutely asinine! That is NOT the justice of God, and we decree that this judge will be deposed and replaced by someone who actually has respect & reverence for God's justice and for the constitution! (I said deposed on purpose because this judge obviously thinks he can decide whatever he wants in spite of the law.)

2 0 Reply • Share ›

stevor
3 days ago
allowing that long is RIDICULOUS! Are they hoping that fauXi will finally DIE so they won't have to deal with him on trial for Crimes Against Humanity?

2 0 Reply • Share ›

bernard b carman → stevor
2 days ago
i would not be surprised if Fauci were to "commit suicide" in some mysterious way as did Jeffrey Epstein.

0 0 Reply • Share ›

jann
6 hours ago
Gee, the FDA has an unusually high number of FOIA requests since the rollout of the shot. A year and half more to release what should have been released four years ago or whenever the shot was actually invented. Maybe the money used to hire extra IRS agents could be re-appropriated for the FDA. And the FDA thinks it's above even a U.S. Senator. Unbelievable.

0 0 Reply • Share ›

bernard b carman
2 days ago
"Active monitoring is essential because it allows us to assess potential associations between vaccine exposure and adverse events in near-real time," — if this is even remotely true, then there is absolutely no just excise for this waiting game.

0 0 Reply • Share ›

Gary Brown
2 days ago

Children's Health Defense

Children's Health Defense® is a 501(c)(3) non-profit organization. Our mission is to end childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable and establish safeguards to prevent future harm. We fight corruption, mass surveillance and censorship that put profits before people as well as advocate for worldwide rights to health freedom and bodily autonomy.

THE DEFENDER IS AVAILABLE IN:
ENGLISH SPANISH PORTUGUESE GERMAN ITALIAN FRENCH

TAKE ACTION
DONATE FREE SIGN-UP BECOME A MEMBER

Donations are tax deductible to the full extent of the law. EIN #26-0388604

© 2016 - 2023 Children's Health Defense® • All Rights Reserved • Sitemap